WSA 2002 Proposed Project Plan

NO1330

Project Name:	A Single Center Study to Evaluate the Short Term Exposure to Smoke Constituents of Conventional Cigarettes and EHCCS-(JLI) Cigarettes in Adult Smokers
Objectives:	• Measure biomarkers of exposure in adult smokers switching from conventional cigarettes to the JLI cigarette for a period of 8 days. • Determine whether smokers who switch from low-tar cigarettes to the Accord (JLI) cigarette have a change of exposure to certain tobacco smoke constituents
Deliverable(s):	Report and publications
Reason for Doing this Work:	Contribute to the development of a reduced harm cigarette product and contribute to the understanding of smoking and health
Program Area: (Select One)	☐Cancer ☐CVD ☐COPD ☐Repro ☐ETS ☐Smoking Behavior ☒Clinical Testing ☐Communication ☐Acceptability Assessment ☐R.H. Evaluation ☐R.H. Guidance ☐Non-Clinical Testing ☐Non-Clinical Research
Project Leader:	Bettie L. Nelson

Tactics and Milestones:	Target Date:
• Complete contracts with CRO	December 14, 2001
• Develop protocol and Informed Consent forms	December 20, 2001
• Final protocol completed	December 21, 2001
• Submit Informed Consent form to IRB	January 4, 2002
• Develop Investigator Brochure	January 7, 2002
• Begin recruitment	January 15, 2001
• Begin study enrollment	February 15, 2002
• Clinical performance	February 15-28, 2002
• Biomarker analysis	March 4-June 28, 2002
• Data base lock	July 31, 2002
• Preliminary report	August 30, 2002
• Final report' and publication schedule	September 30, 2002

Internal Resource Allocation (WSA, INBIFO)	External Resource Allocation (other PMUSA, external vendors)
H. Roethig (60 hrs); R. Kinser (150 hrs); B. Nelson (240 hrs); R Elves (25 hrs); C. Adams (120 hrs) D. Himikel (120 hrs); R. Lau (120 hrs); D. Newman (20 hrs)	MDSPS; Covance; ABF

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